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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,881	02/16/2001	Marinus Petrus de Baar	4760US	4204

7590 04/09/2003

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/785,881	De Barr
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 29, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 16-18, and 21-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-9, 16-18, and 21-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-9, 16-17 and 21-25 are rejected under 35 U.S.C. 103 (a) over Saiki et al. (U.S. Patent 4,683,194) (July 28, 1987) in view of Dattagupta (U.S. Patent 5,215,899) (June 1, 1993).

Saiki et al teach a method for reducing background signals in a hybridization reaction of nucleic acids involving probes (Abstract and Column 6, line 65 to column 7, line 28 and Column 3, line 58 to Column 4, line 5), the method comprising:

introducing a mismatch with an intended target sequence in the probe (Column 6, line 65 to Column 7, line 15); and

conducting a hybridization reaction using the at least two homologous probes (column 7, lines 16- 28).

Saiki et al teach a method in which the probes are designed to detect point mutations in at least one target sequence (Abstract and Claim 15).

Saiki et al teach a method, wherein the mismatch in a nucleotide sequence comprises 1-3 nucleotides (Column 7, lines 19-25 and Claims 16 and 21 and Figure 4).

Saiki et al teach a method, wherein the mismatch in a nucleotide sequence is located between 2 and 20 nucleotides upstream or downstream of a point mutation (Figure 4).

Saiki et al teach a method of conducting a hybridization reaction (Abstract) comprising:

mixing a set of probes for detecting at least one allelic variant of a nucleic acid, wherein at least one set of probes comprise at least one sequence completely complementary to and specific

for one of the allelic variants of the nucleic acid, except for a specific mismatch located downstream from the site of variation (Column 3, line 58 to Column 4, line 5 and Figure 4);

detecting variants of the nucleic acid (Column 4, lines 18-19 and Claim 15); and

using the set of probes to conduct the hybridization reaction (Abstract, Claim 15 and Column 3, line 58 to Column 4, line 20 and Column 6, line 65 to column 7, line 28).

Saiki et al teach a method, wherein the nucleic acids are derived from a group of pathogens (Column 10, line 59 to column 11, line 6).

Saiki et al teach a method, wherein one of the probes is provided with a detectable moiety (Figure 4).

Saiki et al do not teach a method, wherein at least two homologous probes are used and at least one of the homologous probes is a non-linear probe.

Dattagupta teaches a method, wherein at least two homologous probes are used and at least one of the homologous probes is a non-linear probe (Example 1 and Claims 1-40 and Column 5, lines 28-67).

Saiki et al do not teach a method, wherein at least one non-linear probe has a length from about 15 to about 50 nucleotides.

Dattagupta teaches a method, wherein at least one non-linear probe has a length from about 15 to about 50 nucleotides (Column 5, lines 6-48).

Saiki et al do not teach a method, wherein at least one non-linear probe is provided with a detectable moiety.

Dattagupta teaches a method, wherein at least one non-linear probe is provided with a detectable moiety (Claims 18 and 20).

Saiki et al do not teach a method of amplifying a nucleic acid sequence.

Dattagupta teaches a method of amplifying a nucleic acid sequence. (Figure 4 and Column 10, line 51 to Column 11, line 23)

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the non-linear probe of Dattagupta in the method of detection of polymorphic sites in a nucleic acid sequence of Saiki et al since Dattagupta states, "In particular, the invention concerns methods for detecting the presence of a particular nucleic acid sequence with high sensitivity (Column 1, lines 13-15)". An ordinary practitioner would have been motivated to substitute and combine the non-linear probe of Dattagupta in the method of detection of polymorphic sites in a nucleic acid sequence of Saiki et al in order to achieve the express advantages , as noted by Dattagupta, of an invention which provides methods for detecting the presence of a particular nucleic acid sequence with high sensitivity.

4. Claim 18 is rejected under 35 U.S.C. 103 (a) over Saiki et al. (U.S. Patent 4,683,194) (July 28, 1987) in view of Dattagupta (U.S. Patent 5,215,899) (June 1, 1993) further in view of Cronin et al. (U.S. Patent 6,027,880) (February 22, 2000) .

Saiki et al. in view of Dattagupta teach the method of claims 1-9, 16-17, and 21-25 as described above.

Saiki et al. in view of Dattagupta do not teach the method, wherein the nucleic acids represent a number of HIV-variants.

Cronin et al. teach the method, wherein the nucleic acids represent a number of HIV-variants (Column 18, lines 20-26).

It would have been *prima facie* obvious to one having ordinary skill in the art 2.at the time the invention was made to substitute and combine the nucleic acids representing a number of HIV-variants of Cronin et al. in the method of detection of polymorphic sites in a nucleic acid sequence of Saiki et al in view of Dattagupta, since Cronin et al. state, "Such capacity is valuable, e.g., for diagnosis of patients who are heterozygous with respect to a gene or who are infected with a virus, such as HIV, which is usually present in several polymorphic forms (Column 18, lines 23-26) ". An ordinary practitioner would have been motivated to substitute and combine the nucleic acids representing a number of HIV-variants of Cronin et al. in the method of detection of polymorphic sites in a nucleic acid sequence of Saiki et al in view of Dattagupta , as noted by Cronin et al. , of a method which provides capacity valuable for diagnosis of patients who are heterozygous with respect to a gene or who are infected with a virus, such as HIV, which is usually present in several polymorphic forms.

Response to Arguments

5. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634

ARUN K. CHAKRABARTI
PATENT EXAMINER

March 13, 2003